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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Paul C. Harris and Brian Richards

Application No.: 10/714,318 Group Art Unit: 1641

Filed: November 14, 2003 Examiner:

Confirmation No.: 9689

Title: COMPENSATION FOR VARIABILITY IN SPECIFIC
BINDING IN QUANTITATIVE ASSAYS.

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
6/8/04	Katie Norris
Date	Signature
Katie Norris	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:
☐ a Statement under 37 CFR 1.97(e), as checked below, or
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:
☐ a Statement under 37 CFR 1.97(e), as checked below, and
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

☒ Enclosed herewith is form PTO-1449:

- ☐ Copies of the cited references are enclosed.
 - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/817,781, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

David E. Brook for R.N. 22592

By *Elizabeth W. Mata*

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Dated: *6/9/04*

PTO-1449 REPRODUCED

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

June 8, 2004

(Use several sheets if necessary)

 ATTORNEY DOCKET NO.
2065.2001-006

 APPLICATION NO.
10/714,318

 FIRST NAMED INVENTOR
Paul C. Harris

 FILING DATE
November 14, 2003

EXAMINER

CONFIRMATION NO.

 GROUP
1641

U.S. PATENT DOCUMENTS

EX- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,356,782	10-18-1994	Moorman, <i>et al.</i>
	AB	5,384,264	01-24-1995	Chen, <i>et al.</i>
	AC	5,458,852	10-17-1995	Buechler
	AD	5,506,114	04-09-1996	Sangha
	AE	5,569,589	10-29-1996	Hiraoka, <i>et al.</i>
	AF	5,569,608	10-29-1996	Sommer
	AG	5,610,077	03-11-1997	Davis, <i>et al.</i>
	AH	5,622,871	04-22-1997	May, <i>et al.</i>
	AI	5,648,274	07-15-1997	Chandler, <i>et al.</i>
	AJ	5,656,503	08-12-1997	May, <i>et al.</i>
	AK	5,753,517	05-19-1998	Brooks, <i>et al.</i>
	AA2	5,851,048	12-22-1998	Fujita, <i>et al.</i>
	AB2	5,885,527	03-23-1999	Buechler
	AC2	6,133,048	10-17-2000	Penfold, <i>et al.</i>
	AD2	5,141,850	08-25-1992	Cole, <i>et al.</i>
	AE2	6,103,536	08-15-2000	Geisberg
	AF2	6,136,610	10-24-2000	Polito, <i>et al.</i>
	AG2	6,436,721	08-20-2002	Kuo, <i>et al.</i>
	AH2			
	AI2			
	AJ2			
	AK2			
	AA3			
	AB3			
	AC3			

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION June 8, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2065.2001-006	APPLICATION NO. 10/714,318	
	FIRST NAMED INVENTOR Paul C. Harris		FILING DATE November 14, 2003
	EXAMINER	CONFIRMATION NO.	GROUP 1641

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION	
					YES	NO
	AL	WO 88/08534	11-03-1988	Unilver		
	AM	WO 93/03175	02-18-1993	Serex		
	AN	WO 97/09620	03-13-1997	Agen Biomedical Limited		
	AO	WO 99/35602	07-15-1999	Biosite Diagnostics, Inc.		
	AP	EP 0 895 084 A2	03-02-1999	Bayer Corporation		
	AQ	WO 00/31538	06-02-2000	Praxsys Biosystems		
	AL2					
	AM2					
	AN2					
	AO2					
	AP2					
	AQ2					
	AL3					
	AM3					
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	AO3					
	AP3					
	AQ3					
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	AN4					
	AO4					
	AP4					
	AQ4					

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	FIRST NAMED INVENTOR Paul C. Harris		FILING DATE November 14, 2003	
	EXAMINER		CONFIRMATION NO.	GROUP 1641

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Reeves, S.G. and Durst, R.A., "Novel Optical Measurement Approach for the Quantitation of Liposome Immunomigration Assays," <i>Analytical Letters</i> , 28(13):2347-2362 (1995).	
AS	Melamies, L., <i>et al.</i> , "Evaluation of a Quantitative Photometric Latex Agglutination Immunoassay for α -Foetoprotein," <i>J. Clin. Chem. Clin. Biochem.</i> , 25(3):173-176 (1987).	
AT	Abe, J., <i>et al.</i> , "Rapid Quantitation of Serum Myoglobin by Latex Agglutination Turbidimetry," <i>Clinica Chimica Acta</i> , 203:95-96 (1991).	
AU	Borque, L., <i>et al.</i> , "Automated Quantitative Nephelometric Latex Immunoassay for Determining Ferritin in Human Serum," <i>J. Clin. Lab. Analysis</i> , 6:239-244 (1992).	
AV	Roberts, M.A. and Durst, R.A., "Investigation of Liposome-Based Immunomigration Sensors for the Detection of Polychlorinated Biphenyls," <i>Anal. Chem.</i> , 67(3):482-491 (1995).	
AW	Siebert, S.T.A., <i>et al.</i> , "Liposome Immunomigration Field Assay Device for Alachlor Determination," <i>Analytica Chimica Acta</i> , 282:297-305 (1993).	
AX	Siebert, S.T.A., <i>et al.</i> , "Improved Liposome Immunomigration Strip Assay for Alachlor Determination," <i>Analytica Chimica Acta</i> , 311:309-318 (1995).	
AY	Schifreen, R.S., <i>et al.</i> , "A Quantitative Automated Immunoassay for Fibrinogen/Fibrin Degradation Products," <i>Clin. Chem.</i> , 31(9):1468-1473 (1985).	
AZ	Laitinen, M.P.A. and Vuento, M., "Immunochromatographic Assay for Quantitation of Milk Progesterone," <i>Acta Chemica Scandinavica</i> , 50:141-145 (1996).	
AR2	Findlay, J.W.A., <i>et al.</i> , "Validation of immunoassays for bioanalysis: a pharmaceutical industry perspective", <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 21(6):1249-1273 (2000).	
AS2	Paek,S.H., <i>et al.</i> , "Development of Rapid One-Step Immunochromatographic Assay", <i>Methods</i> , 22(1):53-60 (2000).	
AT2		
AU2		

EXAMINER	DATE CONSIDERED
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